



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,244	08/22/2003	Gust H. Bardy	020.0338.US.CON	9403

22895 7590 10/19/2004

PATRICK J S INOUE P S
810 3RD AVENUE
SUITE 258
SEATTLE, WA 98104

EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,244

Applicant(s)

BARDY, GUST H.

Examiner

Carl H. Layno
10/17/04

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11-14, 23-26, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 2-10, 15-22 and 27-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>various</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application Serial No. 09/860,987, filed May 18, 2001, which is a continuation of U.S. Patent No. 6,280,380, which is a Continuation-In-Part of U.S. Patent No. 6,221,011, filed on July 26, 1999.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on August 22, 2003, September 26, 2003, December 15, 2003, March 18, 2004, April 30, 2004, and August 2, 2004.

Drawings

3. Applicant's formal drawings were received by the Office on August 22, 2003 have been approved by the Examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

Art Unit: 3762

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 13, 14, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al '844.

The Walker et al '844 patent describes a system for patient care delivery (Fig.1) comprising a plurality of medical devices **120** for obtaining physiological data from patients and transmitting this data to a central server **200** (col.4, lines 14-23). The server **200** includes a patient database **600** for storing patient medical histories, a database for storing physiological events **700** (Fig.7), and a reaction database **300** for storing treatments for these events (Fig.3). The system creates and stores baseline profiles for individual patients over a period of time (col.4, lines 1-6) and updates these profiles periodically (col.13, lines 11-13).

In regard to claims 13 and 25, the Walker et al system identifies and stores ventricular fibrillation events R31 (Fig.3); hence, "ventricular electrical activity" is one of the "reference measures" used.

Art Unit: 3762

In regard to claim 26, the server **200** includes software code **1200** (Fig.2) for activating the system of claim 1 and performing the method of claim 14. This software is stored in readable medium **250** (Fig.2), which is accessible by a processor **220**.

6. Claims 1, 11-14, 23-26, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Finkelstein et al '923.

The Finkelstein et al '923 patent describes a system and method for remotely monitoring asthma severity (Fig.2) comprising a medical device **120** having a spirometer **124** for measuring a patient's respiratory capacity. The device **120** includes transmission circuits **130** for facilitating wireless or landline communications over a network to a server **172** connected to a plurality of databases **174,176,178**. In use, the Finkelstein et al system uses the spirometer **124** to measure 29 different patient respiratory parameters from forced vitality capacity (FVC) tests (See Fig.3). These FVC parameters are considered applicant's physiological "measured sets". These test results are recorded **450** in memory (Fig.4) and displayed to evaluating physicians **470** (Fig.4) using a graphical user interface (GUI) **300** (Fig.3). The graphical user interface displays test results **320** with recent results superimposed over baseline results (col.8, lines 11-14), and with data in tabular form with baseline predicted results **333** versus actual measured results **334**, the difference in percentages **338** (col.8, lines 52-53).

In regard to claims 11, 23, and 33, the system of Finkelstein et al includes a diagnosis/evaluation station **180**, which performs the function of applicant's "analysis module". A physician at this station **180** compares previous data with new data graphically using

Art Unit: 3762

superimposition of FVC curves to generate messages regarding a patient's respiratory status (col.7, lines 21-36).

In regard to claims 12, 24, and 34, GUI interface **300** (Fig.3) permits the physician to also view comparisons between baseline and present values of any one of 29 FVC parameters to help further assess a patient's status.

In regard to claims 13 and 25, the "reference measures" of Finkelstein et al are "pulmonary measures".

Allowable Subject Matter

7. Claims 2-10, 15-22, and 27-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

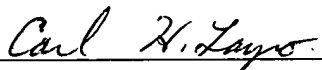
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's Official FAX number (703) 872-9303.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

A handwritten signature in cursive script, reading "Carl H. Layno", is written over a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
10/18/2004